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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,414	09/23/2005	Ryuji Ueno	278283US0X PCT	2194

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EXAMINER	
RAMACHANDRAN, UMAMAHESWARI	
ART UNIT	**PAPER NUMBER**
1617	

NOTIFICATION DATE	DELIVERY MODE
08/13/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/550,414	UENO ET AL.	
	Examiner	Art Unit	
	Umamaheswari Ramachandran	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-45* is/are pending in the application.

4a) Of the above claim(s) *35 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner notes the receipt of the amendments and remarks received in the office on 5/29/2007 canceling claims 1-30 and adding new claims 31-45. Claims 35 and 37 are withdrawn from consideration as the species elected by the Applicants' is found in prior art. Since applicant has received an action on the merits for the originally presented invention Group II, claims 1-10, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 35 and 37 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP 821.03. Claims 31-45 are pending.

Response to Remarks

The rejection of claims under 35 U.S.C 112 first paragraph, 102 (b) and 102(e) rejections are moot in view of Applicants' cancellation of claims 1-30. The double patenting rejection is maintained. The new claims necessitated the modified ground(s) of rejection presented in this Office action. The office action is made final.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 31-34, 36, 38-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of 24, 26, 29, 30-33, 37, 38, 42 of copending Application No. 11/505321. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application teaches a method of treating a vascular hyperpermeable disease (except macular edema) and the copending application teaches a method of treating all VAP-1 associated diseases.

The instant application (claims 31-34, 36, 38-45) is directed to a method of treating vascular hyperpermeable disease such as diabetic retinopathy, comprising administering a vascular adhesion protein-1 (VAP-1) inhibitor. The elected species of the instant application is the compound N-{4- [2-(4- {[amino(imino)methyl] amino } phenyl)ethyl] -5 - [4-(methylsulfonyl)benzyl] - 1,3- thiazol-2-yl} acetamide. The copending application (claims 37, 38, 24-32, 42) teaches a method of treatment of VAP-1 associated disease such as retinopathy (in diabetes patients) comprising administering VAP-1 inhibitor compounds. The copending application (claim 42) further teaches a method of inhibiting VAP-1 or treating VAP-1 associated disease comprising administering the elected species of the instant application, N-{4- [2-(4- {[amino(imino)methyl] amino } phenyl)ethyl] -5 - [4-(methylsulfonyl)benzyl] - 1,3-thiazol-2-yl} acetamide. Hence it is obvious to treat diabetic retinopathy, a vascular permeable disease by administering a VAP-1 inhibitor as claimed in the instant application as the copending application teaches a method to treat all vascular permeable disease by administering VAP-1 inhibitors.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 31-34, 36, 38-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Inoue et al (U.S. 7,125,901). The reference teaches that VAP-1 inhibitors are useful in the treatment of VAP-1 associated disease (col. 2, lines 62-65). The reference further teaches the elected species N-{4- [2-(4- {[amino(imino)methyl] amino } phenyl)ethyl] -5 - [4-(methylsulfonyl)benzyl] -1,3-thiazol-2-yl} acetamide and also the compound N-{4-[2-(4 - { [amino (imino)methyl] amino } phenyl)ethyl] - 1,3-thiazol-2-yl } acetamide (in claim 10 of the instant application) as a VAP-1 inhibitor, and the use of such compounds in the treatment of VAP-1 associated disease such as retinopathy (in diabetes patients) (col. 6, lines 3-27). The reference further teaches that the VAP-1 inhibitor can be administered to the subject as a prodrug and as a pharmaceutically acceptable salt (col. 14, lines 34-41).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art

under 35 U.S.C. 102(e). (The effective filing date of the application is 3/31/2003 and the effective filing date of the reference is 1/27/2003). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Response to Arguments

Applicants' argue that Provisional Application No. 60/442, 509, filed Jan 27 2003 merely describes macular edema as a subject for treatment using VAP-1 inhibitors and there is no disclosure of treatment of vascular hyperpermeable disease is found. In response, the provisional application teaches the elected species as VAP-1 inhibitor (p 3, lines 8-10). The provisional application further teaches that "A recent report has documented that VAP-1 enzyme activity in plasma increases in diabetic patients, whether type I or type II, and the increase is particularly remarkable in diabetic patients suffering from retinopathy complications" (p2, lines 19-24). This clearly teaches the use of VAP-1 inhibitors in the treatment of a complication such as retinopathy in diabetes patients.

Conclusion

No Claims are allowed.

Applicant's addition of new claims necessitated the rejections presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER